

**Citation:**

Abrams, Steven A et al Effect of Prebiotic Supplementation and Calcium Intake on Body Mass Index, J Pediatr 2007;151:293-8

**PubMed ID:** [17719942](#)

**Study Design:**

Randomized Control Trial, blinded

**Class:**

A - [Click here](#) for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine the effects of prebiotic supplementation on weight and body composition changes during puberty, compared to usual diet. Hypothesis: Calcium and prebiotic supplementation would be related to changes in total body fat, BMI, BMI Z-score and that higher calcium intake would enhance prebiotic effect on BMI.

**Inclusion Criteria:**

Age: 9-13 years of age

Non Obese

Tanner stage 2-3 (females were premenarchal)

**Exclusion Criteria:**

None stated

**Description of Study Protocol:**

**Recruitment :** Public Advertisement

**Design:** Double blinded, randomized control trial . Stratified by sex

**Blinding used (if applicable) :** Double blind. Intervention group was given a prebiotic supplement, control group was given maltodextrin supplement, Both groups were instructed to mix supplement in orange juice. Supplement provided 8g/d of either prebiotics or maltodextrin.

## **Intervention (if applicable): Prebiotic supplement containing oligofructose and inulin (8/d)**

### **Statistical Analysis:**

- Statistical comparisons between two groups were made using a generalized linear model (analysis of variance).
  - principle model included initial height Z-score, Tanner breast stage after 1 year, and the calcium and energy intake after 1 year; only energy intake and prebiotic use interaction were included in final model because it was statistically significant
  - effect of calcium intake on changes in body composition was assessed by including this as a continuous independent variable or a dichotomous independent variable (with cut-offs of either 700 mg/d, 800 mg/d., or 900 mg/d)
- changes in body composition over the year of study were also evaluated: BMI z-score at the start and end of the study were compared in each of the 2 groups individually with a paired t-test
- Data was presented as mean and SD, with significance reported a p < 0.05.
- For each analysis, the final value was used as the dependent variable, and the initial value used as a covariate

### **Data Collection Summary:**

#### **Timing of Measurements:**

Baseline within 8 weeks of eligibility screening and 1 year following supplementation: physical assessments, dietary history, and 2-day food records

Every 2 months and at 2 year follow-up: telephone 24-hour recall of previous day's intake

#### **Dependent Variables: Dependent variables were defined as final measures of the following:**

- Body fat: measured using DXA absorbtometry
- BMI Z score and BMI were obtained using weight and height measures by standard technique and calculated from an online database.

#### **Independent Variables:**

- prebiotic supplement versus placebo
- calcium intake: Intake of energy and calcium from 24 hour recall and inpatient 24 hour weighed intake

**Covariate:** Initial value for above data.

### **Description of Actual Data Sample:**

**Initial N:** 100 (50 prebiotic group, 50 control group)

## Attrition

- N=97 (48 prebiotic group, 49 control group) at 1 year
- N=89 for 2 year followup (note outcome measures were reported at 1 year for N of 97)

**Age:** Prebiotic Group ( $11.8 \pm 0.2$  years) Control Group ( $11.4 \pm 0.2$  years), P=0.02

**Ethnicity:** Not specifically described. Study was designed to match the ethnic distribution of the Houston area.

## Other relevant demographics:

### Anthropometrics:

- BMI ( $\text{kg}/\text{m}^2$ ): Prebiotic group:  $18.99 \pm 0.37$ ; Non-prebiotic group:  $18.62 \pm 0.37$
- BMI Z-score: Prebiotic group:  $0.26 \pm 0.18$ ; Non-prebiotic group:  $0.20 \pm 0.18$

no significant differences in baseline Weight, height, BMI (and Z score), percent body fat, total fat mass, calcium or energy intake.

**Location:** Houston , Clinical Research Center of Texas Children's Hospital

## Summary of Results:

### Key Findings

- The increment in BMI over the study year was  $0.73 \text{ kg}/\text{m}^2$  for the prebiotic group, and  $1.24 \text{ kg}/\text{m}^2$  for the control group (difference  $0.52 \pm 0.16 \text{ kg}/\text{m}^2$ , P=0.016). Omitting calcium intake from the analysis negligibly changed the relative prebiotic effect on BMI by  $0.01 \text{ kg}/\text{m}^2$ .
- There was no significant increase in BMI Z-score in the prebiotic group during the study ( $0.03 \pm 0.01$ , P=0.30); the BMI-Z-score increased significantly in the control group ( $0.13 \pm 0.04$ , P=0.001)
- There was a trend towards significance for the effect of calcium intake on BMI and BMI Z-score when calcium intake was considered as a continuous linear covariate. However, when calcium intake was dichotomized (at 700, 800, or 900 mg/d) a highly significant (P<0.01) effect of calcium intake on BMI and BMI Z-score was seen in a model with 700 mg/d and 800 mg/d as cutoff points. Changes in BMI, BMI Z-score, fat mass, and weight over the study year were significantly less for subjects above the calcium intake cutoff point than for those below it. Changes were not significant at the 900 mg/d cutoff point.
- Use of the prebiotic had no significant effect on body composition outcomes for calcium intakes < 700 mg/day.
- In subjects with calcium intakes  $\geq 700 \text{ mg}/\text{d}$ , the prebiotic supplementation was associated with a BMI difference of  $0.82 \text{ kg}/\text{m}^2$ , BMI Z-score difference of 0.2, fat mass difference of 1.3 kg, and a body weight of 2.0 kg, compared with those not receiving the prebiotic (values lower for prebiotic group, all P<0.01, except BMI, P<0.001)
- At 2 year follow-up, 1 year post-intervention, there was a BMI difference of  $0.68 \pm 0.36 \text{ kg}/\text{m}^2$ , P=0.061 for the prebiotic effect, and  $0.91 \pm 0.41$ , P=0.03 for the calcium effect on BMI (lower values in those who received prebiotic and those who had a calcium intake  $\geq 700 \text{ mg}/\text{d}$ )

Variables	Treatment Group mean $\pm$ s.d.	Control group mean $\pm$ s.d.	Statistical Significance of Group Difference
BMI Z-score	0.25 $\pm$ 0.045	0.38 $\pm$ 0.044	0.048
BMI (kg/m squared)	19.52 $\pm$ 0.15	20.03 $\pm$ 0.015	0.016
% body fat	23.3 $\pm$ 0.4	24.2 $\pm$ 0.4	0.14
total fat mass	11.24 $\pm$ 0.25	12.07 $\pm$ 0.25	0.022

### Other Findings:

### Author Conclusion:

Prebiotic supplementation and avoidance of a low calcium intake has significant effects in modulating BMI and other body composition changes during puberty.

### Reviewer Comments:

Weel designed study. Limitations include small sample size with multiple repeat analysis. Used 2 different models for analysing the effect of calcium (one was statistically significant, other was not). There are limits to the interpretation of these results as adolescence is a time of dynamic growth and changes in body composition. Changes in BMI and BMI z-scores reflect changes in body composition including fat, muscle, bone density. These changes are different for male vs females. As none of these patients were obese, it would be difficult to conclude whether these differences are positive or negative (or neutral). Description of statistical analysis was not complete as tests used to determine significance was not reported.

### Research Design and Implementation Criteria Checklist: Primary Research

#### Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) Yes
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? Yes
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? Yes
4. Is the intervention or procedure feasible? (NA for some epidemiological studies) Yes

#### Validity Questions

<b>1.</b>	<b>Was the research question clearly stated?</b>	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
<b>2.</b>	<b>Was the selection of study subjects/patients free from bias?</b>	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
<b>3.</b>	<b>Were study groups comparable?</b>	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
<b>4.</b>	<b>Was method of handling withdrawals described?</b>	Yes
4.1.	Were follow-up methods described and the same for all groups?	???
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%).	Yes

4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
<b>5.</b>	<b>Was blinding used to prevent introduction of bias?</b>	
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
<b>6.</b>	<b>Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening/factors described?</b>	
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
<b>7.</b>	<b>Were outcomes clearly defined and the measurements valid and reliable?</b>	
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes

7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
<b>8.</b>	<b>Was the statistical analysis appropriate for the study design and type of outcome indicators?</b>	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
<b>9.</b>	<b>Are conclusions supported by results with biases and limitations taken into consideration?</b>	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
<b>10.</b>	<b>Is bias due to study's funding or sponsorship unlikely?</b>	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	???

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